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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,466	03/02/2000	James L. Hartley	0942.4680003/RWE/BJD	4289

26111 7590 03/28/2005

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WASHINGTON, DC 20005

EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/517,466

Applicant(s)

HARTLEY ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 39-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ELECTION/RESTRICTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21, 2005 has been entered.
2. Upon entry of the amendment of January 21, 2005, it is noted that all previously pending claims (1-38) have been canceled, and that new claims 39-56 have been added. As the prior restriction requirement of March 27, 2002 is not applicable to the new claims, that restriction requirement is hereby withdrawn, and a new requirement is set forth below.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 39-49, drawn to nucleic acids, vectors, and host cells, classified in class 536, subclasses 23.1 and 24.1, and class 435, subclasses 252.3, 320.1, and 325.
 - II. Claims 50-51, drawn to a method of generating a nucleic acid molecule using amplification, classified in class 435, subclass 91.2.
 - III. Claims 52-56, drawn to a method of recombining nucleic acid molecules, classified in class 435, subclass 91.5.
4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, and I and III, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products of Invention I can be used in a materially different process, such as protein synthesis. Further, searching Invention I and II together, or I and III together, would impose serious search burden. The inventions have a separate status in the art as shown by their different classifications. Additionally, the searches required for each Invention are not coextensive. For example, Invention I requires a search for a variety of products other than nucleic acids, including vectors and host cells, while each of Inventions II and III requires a search for particular method steps. Prior art teaching a polynucleotide of Invention I would not necessarily be applicable to the methods of Invention II or III. Moreover, even if a polynucleotide product of Invention I were known, methods using the product may be novel and unobvious in view of the preamble or active steps of Invention II or III.

Inventions II and III are patentably distinct methods requiring different method steps to achieve different objectives. Invention II requires steps of, e.g., nucleic acid amplification using particular primers to achieve the objective of generating a nucleic acid amplification product, while Invention III requires steps of, e.g., preparing and incubating a mixture comprising particular nucleic acid molecules to accomplish the goal of recombination. Further, searching Inventions II and III together would impose serious

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search burden. The inventions have a separate status in the art as shown by their different classifications. Additionally, the searches required for each Invention are not coextensive. Specifically, Invention II requires a search for a primer comprising a particular sequence as well for methods of amplification employing said primer, while Invention III requires a search for one or more nucleic acid molecules comprising particular sequences and method steps of reaction mixture preparation and incubation employing said molecules.

Sequence Election Requirement Applicable to All Groups

5. In addition, each Group detailed above encompasses multiple patentably distinct sequences and/or sequence combinations (see the sequences set forth as (a)-(l) in each of independent claims 39, 50, and 52). Each of these molecules is patentably distinct because the sequences are structurally different and unrelated, necessitating a separate and different search for each molecule. Such molecules are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. A reference against one molecule would not be a reference against another, and, in view of this and the multitude of sequences submitted for examination by the USPTO, a search of multiple distinct sequences or sequence combinations as set forth in Inventions I-III would pose a serious burden. Accordingly, a further restriction is applied to each Group:

- a) If either of **Inventions I or II** is elected, Applicant must further elect a single one of the sequences set forth as (a)-(l) for examination.

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b) If **Invention III** is elected, Applicant may elect either one sequence set forth as (a)-(l) (i.e., elect the embodiment of the invention in which each nucleic acid molecule of the claims comprises the same nucleotide sequence of (a)-(l)), or elect multiple sequences from (a)-(l), and further specify two particular combinations of sequences selected from (a)-(l). For example, Applicant could elect a first nucleic acid molecule comprising the sequences of (a) and (b), and a second nucleic acid molecule comprising the sequences of (c), (d), and (e), for examination. It is noted that the claims of Invention III as written encompass the use of thousands of different molecules comprising one or more of the sequences of (a)-(l). Each of these molecules is structurally distinct and would require a separate and different search as compared to every other such molecule; accordingly, examination of more than one such sequence or sequence combination would pose a serious burden.

Applicant is advised that examination will be restricted to only the elected sequence(s) and should not to be construed as a species election.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-III require different searches that are not coextensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

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7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "Diana B. Johannsen". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Diana B. Johannsen
Primary Examiner
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March 23, 2005